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Arexvy (*Respiratory Syncytial Virus (RSV) vaccine (recombinant, adjuvanted)*)

An overview of Arexvy and why it is authorised in the EU

What is Arexvy and what is it used for?

Arexvy is a vaccine for adults 60 years of age and older to protect them against lower respiratory tract disease (LRTD; diseases of the lungs such as bronchitis or pneumonia) caused by respiratory syncytial virus (RSV).

Arexvy contains a version of a protein found on the surface of the virus called RSVPreF3.

How is Arexvy used?

The recommended dose is one single injection into a muscle.

The vaccine can only be obtained with a prescription and should be used according to official recommendations issued at national level by public health bodies.

For more information about using Arexvy, see the package leaflet or contact your doctor or pharmacist.

How does Arexvy work?

Arexvy works by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. Arexvy contains a protein from the surface of the RSV virus. When a person is given the vaccine, the immune system treats the virus proteins as 'foreign' and makes defences against them. If, later on, the vaccinated person comes into contact with the virus, the immune system will recognise the virus proteins and be prepared to attack it. This will help to protect against LRTD caused by the virus.

What benefits of Arexvy have been shown in studies?

In a study in over 25,000 adults aged 60 years and above, people who received Arexvy had an 83% reduction in their risk of getting LRTD caused by RSV compared with those who had a dummy injection.

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In the group who received Arexvy, 7 out of 12,466 vaccinated people got LRTD, while in the group who received dummy injections, 40 out of 12,494 people got the disease.

What are the risks associated with Arexvy?

For the full list of side effects and restrictions with Arexvy, see the package leaflet.

The most common side effects with Arexvy (which may affect more than 1 in 10 people) include injection site pain, tiredness, muscle pain, headache and joint pain. These side effects are usually mild or moderate in intensity and resolve within a few days after vaccination.

Why is Arexvy authorised in the EU?

At the time of authorisation of Arexvy, there was no vaccine to prevent RSV and no treatment, other than supportive care, for older adults. The main study showed that Arexvy is effective in preventing RSV-confirmed LRTD in this patient group. By preventing RSV-confirmed LRTD, the vaccine is also expected to reduce the risk of severe RSV disease.

There are no serious safety concerns and the European Medicines Agency therefore decided that Arexvy's benefits are greater than its risks and it can be authorised for use in the EU.

What measures are being taken to ensure the safe and effective use of Arexvy?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Arexvy have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Arexvy are continuously monitored. Suspected side effects reported with Arexvy are carefully evaluated and any necessary action taken to protect patients.

Other information about Arexvy

Arexvy received a marketing authorisation valid throughout the EU on 06 June 2023.

Further information on Arexvy can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/arexvy.

This overview was last updated in 06-2023.